Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

1st OCT 2006

AHWP IS SEEKING VIEWS ON THE PROPOSED COMMON SUBMISSION DOSSIER TEMPLATE (CSDT) GUIDANCE DOCUMENT

The Asian Harmonisation Working Party (AHWP) Technical Committee has drafted a guidance document titled "Common Submission Dossier Template" (CSDT). CSDT is a guidance document intended to be used by all medical device manufacturers (big & small) when submitting device information to the regulatory authorities of AHWP member economies.

2 The proposed guidance document serves to provide guidance for submission of device information to the regulatory authorities; structured in the format of one common template acceptable by all AHWP member economies regulators. It is envisaged that CSDT will:-

- harmonize the differences in documentation formats that presently exist in different AHWP member economies jurisdictions;
- use descriptive text and examples to illustrate concisely the meanings of the submission requirements as it may not be obvious from simply reading the headers;
- provide guidance to all medical device manufacturers, especially small manufacturers in Asia with little or no knowledge of medical device regulatory affairs;
- provide important device information (e.g. device marketing history) to regulators; these information may be useful for both pre-market assessment and post-market surveillance activities.

3 This guidance document can be construed to consist of two parts:-

- components similar to GHTF's SG1 Summary Technical Documentation (STED) for demonstrating conformity to the Essential Principles of Safety and Performance of Medical Devices; and
- additional components containing useful information (e.g. an executive summary).

4 This document applies to all products that fall within the definition of a medical device, as defined by GHTF Study Group 1 in document "SG1-N29R16:2005". As such, it is

proposed that *in-vitro* diagnostic devices be included within the scope of this guidance document.

5 It is hoped that the eventual adoption of this guidance document in AHWP member economies will eliminate the preparation of multiple dossiers, arranged in different formats but with essentially the same contents, for regulatory submission to different regulatory authorities.

6 Asian Harmonisation Working Party is seeking views and feedback from all interested stakeholders from the medical device industry on the proposed CSDT guidance document. Besides seeking your views on the entire guidance document, AHWP will like to seek your views on:-

- the suitability of including *in-vitro* diagnostic devices in CSDT;
- the type and amount of information to be submitted for the various classes of devices in the matrix (draft) described in Section 4.2;

7 There will be a 4-month consultation period, commencing from 1st Oct 2006; comments are welcomed from all interested stakeholders (e.g. industry groups, device manufacturers, government regulators, individuals, etc) within and outside of Asia.

8 The draft CSDT guidance document is available on the AHWP website at "*www.asiahwp.org*". All feedback should be prepared using the comments template, and emailed to the AHWP Secretariat at "*info@asiahwp.org*", by 31st Jan 2007.

9 Asian Harmonisation Working Party may publish responses to this consultation document. Please ensure that your responses are marked clearly if you wish your response or name to be kept confidential. If you consider any information to be confidential or commercially sensitive, please identify it and explain the reasons for its sensitivity.

About the Asian Harmonization Working Party

Asian Harmonization Working Party (AHWP) is established as a non-profit organisation. Its objectives are to forge a common direction for the harmonization of medical device regulations in Asia, encourage increased understanding on the benefits of harmonization and facilitate a linkage with the Global Harmonization Task Force (GHTF). As a regional organisation, AHWP aims to provide a forum for discussion and training, facilitate information exchange and initiate projects relating to GHTF harmonisation among regulators and industry groups in Asia; and seek to establish AHWP as a formal regional grouping under the GHTF. For more details, please visit www.asiahwp.org.

For queries, please contact:

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